

REMARKS

I. INTRODUCTION

Claims 3 and 4 have been cancelled, without prejudice. Claims 1, 11, 12, 18-22, 24, 25, 30, 31 and 33-36 has been amended above to clarify the subject matter recited therein. New claim 44 has been added. Accordingly, claims 1, 2, 5-7, 9, 11-31, 33-36 and 40-44 are under consideration in the above-referenced application. Provided above, please find a claim listing indicating the cancellation of claims 3 and 4, the amendments to claims 1, 9, 11, 12, 18-22, 24, 25, 30, 31 and 33-36, and the addition of new claim 44 on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN

Claims 1-7, 9, 11-31 and 33-35 stand rejected under 35 U.S.C. §112, second paragraph as being allegedly indefinite. As the Examiner shall ascertain, the §112 rejection has been obviated via the clarifying and non-limiting amendments to claims 1, 9, 11, 12, 18-22, 24, 25, 30, 31 and 33-35.

In addition, with respect to the Examiner's comments for claims 21 and 22, these claims certainly recite positive recitations which provide further limitations of the subject matter recited in the claims the claim(s) from which they depend. Further, claims 1, 18, 24 and 30 have been amended to remove any issues with antecedent bases previously presented therein. Further claims 27 and 33 have been amended to address the Examiner's comments.

Therefore, for at least the reasons as set forth herein above, the rejection of claims 1-7, 9, 11-31 and 33-35 under 35 U.S.C. §112, second paragraph should be withdrawn.

III. REJECTION UNDER 35 U.S.C. § 101 SHOULD BE WITHDRAWN

Claims 18-31 and 33-35 stand rejected under 35 U.S.C. § 101 as being allegedly being directed to non-patentable subject matter. (See Office Action dated December 23, 2009, pp. 2-3). Applicants respectfully assert that amended independent claims 18, 24 and 30, and claims 19-23, claims 25-29 and claims 31, 32 and 33-35, which depend from claims 18, 24 and 30, respectively, are certainly directed to patentable subject matter under 35 U.S.C. § 101 for at least the following reasons.

The recent Federal Circuit decision of *In re Bilski* provides the test to be employed for determining whether the claims comply with the requirements of 35 U.S.C. § 101. *In re Bilski*, No. 2007-1130 (Fed. Cir. 2008) (en banc). Specifically, the *In re Bilski* opinion “reaffirm[s] that the machine-or-transformation test outlined by the Supreme Court is the proper test to apply.” *In re Bilski*, p. 20. “To the extent that some . . . decisions relied on considerations or tests, such as ‘useful, concrete and tangible result,’ that are no longer valid as explained above, those aspects of the decisions should no longer be relied on.” *id.*, p. 23. “Thus, we reexamine the facts of certain cases under the correct test to glean greater guidance as to how to perform the § 101 analysis using the machine-or-transformation test.” *id.*, pp. 23-24. “The machine-or-transformation test is a two-branched inquiry; an applicant may show that a process claim satisfies § 101 either by showing that his claim is *tied to a particular machine*, or by showing that his claim *transforms an article*.” *id.*, p. 24 (*emphasis added*).

A) Claims 18-23

The Examiner asserts that, regarding claims 18-23, these claims “are not tied to another statutory category, nor do they positively recite subject matter being transformed, they are directed to non-statutory subject matter.” (Office Action, p. 3).

As the Examiner shall ascertain, independent claim 18 has been amended above to recite:

A method for identifying characteristics of tissue, comprising:

performing an axial scan of the tissue using radiation; and

processing data relating to the axial scan radiation based on the axial scan to identify characteristics of the tissue using an imaging system ...

Applicants respectfully assert that amended independent claim 18, as well as claims 19-23 which depend therefrom, thus certainly recite statutory subject matter.

As an initial matter, amended independent claim 18 certainly includes the recitation which ties the procedure recited therein to a statutory machine, e.g., an imaging system, and thus surely fits squarely in the “**machine**” requirement of *In re Bilski*, thereby satisfying the **machine-or-transformation test**. Further, the recitation of processing data relating to the axial scan radiation based on the axial scan to identify characteristics of the tissue, as also recited in amended independent claim 18, involves a **physical transformation** of data in a machine, thus also satisfying the **machine-or-transformation test** of *In re Bilski*.

Thus, Applicants respectfully assert that amended independent claim 18 certainly recites statutory subject matter, especially since the **machine-or-transformation**

test of *In re Bilski* requires only one branch thereof to be satisfied. (See, e.g., *In re Bilski*, p. 24). However, it is respectfully asserted that amended independent claim 18 complies with both such alternate requirements.

Therefore, for at least the reasons cited above, withdrawal of the rejection of claims 18-23 under 35 U.S.C. § 101 is respectfully requested.

B) Claims 24-29

Further, the Examiner asserts that “[c]laims 24-29 (storage medium) and claims 30, 31 and 33-35 (logic arrangement) ... are improperly drawn to non-statutory subject matter.” (*Id.*).

Independent claim 24 has been amended to recite:

A computer-accessible storage medium storing a software program for identifying characteristics of tissue, wherein the software program, when executed by a processing arrangement, is configured to cause the processing arrangement to execute the procedures comprising of:

causing a performance of an axial scan of the tissue using radiation using a radiation source; and

processing data relating to the axial scan radiation to identify characteristics of the tissue.

Applicants respectfully assert that amended independent claim 24, which recites computer-accessible storage medium, as well as claims 25-29 which depend therefrom, certainly recite statutory subject matter.

As discussed above, the *In re Bilski* case reaffirms that the machine-or-transformation test outlined by the Supreme Court is the proper test to apply and that, to

the extent that some decisions relied on other considerations or tests that are no longer valid, those aspects of the decisions should no longer be relied on. As claim 24 at least recites a computer-accessible storage medium and is tied to a particular machine (e.g., a processing arrangement), independent claim 24 clearly satisfies the machine-or-transformation test of *In re Bilski*. In addition, not only amended independent claim 24 recited computer-accessible storage medium, this claim also has recitations which are tied to another machine, i.e., the processing arrangement and uses the radiation source. Accordingly for such additional reasons, this claim and the claims which depend therefrom are believed to be in full compliance with the machine-or-transformation test as set forth in *In re Bilski*.

Therefore, for at least the reasons cited above, withdrawal of the rejection of claims 24-29 under 35 U.S.C. § 101 is respectfully requested.

B) Claims 30, 31 and 33-35

Regarding independent claim 30, this claim has been amended to recite:

A software arrangement for identifying characteristics of tissue, which, when executed by a processing arrangement, configures the processing arrangement to perform procedures comprising of:

causing a performance of an axial scan of the tissue using radiation using a radiation source; and

processing data relating to the axial scan radiation to identify characteristics of the tissue, wherein a portion of the radiation emitted by the radiation source is directed into a sample arm and radiation reflected from the tissue back is obtained through the sample arm

Applicants respectfully assert that amended independent claim 30, which recites a software arrangement which configures the processing arrangement to perform the procedures, as well as claims 31 and 33-35 which depend therefrom, thus certainly recite statutory subject matter.

As claim 30 recites a processing arrangement which is configured by the software arrangement to perform the procedures recited in that claim, and is thus tied to a particular machine (e.g., the processing arrangement), independent claim 30 clearly satisfies the machine-or-transformation test of *In re Bilski*. In addition, not only amended independent claim 30 recites the processing arrangement, this claim also has the recitations which are tied to another statutory machine, i.e., the radiation source. Accordingly for this additional reasons, this claim is believed to be in full compliance with the machine-or-transformation test as set forth in *In re Bilski*.

Therefore, for at least the reasons cited above, withdrawal of the rejection of claims 31 and 33-35 under 35 U.S.C. § 101 is respectfully requested.

IV. REJECTIONS UNDER 35 U.S.C. §§ 102(b) AND 103(a) SHOULD BE WITHDRAWN

Claims 1-3, 5-7, 9, 11-31, 33-36 and 40-43 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by U.S. Patent No. 6,002,480 issued to Izatt (the "Izatt Patent"). Claim 4 stands rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over the Izatt Patent.

Applicants respectfully assert that the Izatt Patent fails to teach, suggest or disclose the subject matter recited in independent claims 1, 18, 24, 30, 41 and 43, and the claims which depend from independent claims 1, 18, 24 and 30.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; also see *Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

Under 35 U.S.C. § 103(a), a person is not entitled to a patent even though the invention is not identically disclosed or described as set forth in §102, "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the "TSM test"). See *In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit's application of the TSM test, see *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; see *In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, "the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure." *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O'Farrell*, 853 F.2d. 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant's disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. See *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

The Izatt Patent relates to a method for determining depth-resolved backscatter characteristics of scatterers within a sample, in which a plurality of sets of cross-correlation interferogram data are acquired using an interferometer having a sample arm with the sample in the sample arm. The sample includes a distribution of scatterers therein. The distribution of scatterers within the sample is altered with respect to the sample arm for substantially each acquisition. The cross-correlation interferogram data is average, in the Fourier domain, thereby revealing backscattering characteristics of the scatterers within the sample. (See Izatt Patent, Abstract). According to the Izatt Patent, the backscatter spectrum $C(k)$ 98 is transmitted to a computer 100 for comparison against backscatter data from a 'normal' tissue that is stored in the database 101. (See *Id.*, col. 20, Ins. 46-50).

i. Independent Claims 1, 18, 24 and 30 and Dependent Claims

Applicants' invention, as recited in amended independent claim 1, relates to an apparatus for identifying characteristics of tissue which comprises, *inter alia*:

a radiation source configured to perform an axial scan of the tissue using radiation; and

an imaging system adapted to receive axial scan radiation based on the axial scan, and to process data relating to the axial scan radiation to identify characteristics of the tissue ...,

wherein at least one of (i) the radiation source is a swept wavelength optical source or (ii) the radiation source is a broad bandwidth light source and the imaging system includes a spectrometer.

Amended independent claims 18, 24 and 30 relate to method, computer-accessible storage medium and software arrangement, respectively, which recite similar subject matter.

Thus, each of amended independent claims 1, 18, 24 and 30 recites that **the radiation source is a swept wavelength optical source, and/or (ii) the radiation source is a broad bandwidth light source and the imaging system includes a spectrometer.**

In the latest Office Action, the Examiner admits (with respect to now-cancelled claim 4) that the Izatt Patent fails to disclose a swept wavelength optical source. However, the Examiner then contends that because the Izatt Patent describes a source and a bank of filters in column 24 thereof, it would have been obvious to use a swept wavelength optical source instead. (See Office Action, p. 6, para. 9).

Applicants respectfully disagree. Indeed, the Izatt Patent only describes digital filters that are applied after the light has been detected – clearly, the filters of Izatt are not *optical filters*. It would in no way be obvious to one having ordinary skill in the art at the time the present application was filed to substitute the digital filters of the Izatt Patent (which filter data *and not optical radiation*) with the swept wavelength optical source (which *provides optical radiation*). Therefore, the Examiner's contention that it would be obvious to substitute the digital filters and source of the Izatt Patent with the swept wavelength optical source is wholly inaccurate.

In addition, it is respectfully asserted that the Izatt Patent does not teach, suggest or disclose *the detection of the axial scanned data as a function of an optical wavelength of the source*. Thus, at least for this reason, the use of **a broad bandwidth light source with a spectrometer**, as recited in Further, the Izatt Patent has no mention of the use of **a broad bandwidth light source with the imaging system includes a spectrometer**, as recited in amended independent claims 1, 18, 24 and 30.

Accordingly, Applicants respectfully submit that the Izatt Patent does not render the subject matter recited in amended independent claim 1, 18, 24 and 30 anticipated or obvious. The claims which depend from such independent claims are also not taught, suggested or disclosed by the Izatt Patent for at least the same reasons.

In addition, regarding claim 5, the Izatt Patent does not disclose **any insertion device**, much less, **providing the radiation through at least one fiber disposed in such insertion device**. The recitation of claims 6 and 7, which depend from claim 5, are also not disclosed in the Izatt Patent. The subject matter recited in claims 21, 27 and 33 is also not disclosed for at least similar reasons.

Concerning claim 12, the Izatt Patent fails to disclose that the imaging system processes the axial scan radiation by performing **standard deviation, average deviation, and/or slope of the axial reflectivity profile relating to the axial scan radiation**. The subject matter recited in claims 20, 26 and 42 is also not disclosed for at least similar reasons.

Further, with respect to claim 15, the Izatt Patent does not disclose any **statistical model that is a partial least squares and/or principle component analysis**.

ii. Independent Claim 41

Applicants' invention, as recited in independent claim 41, relates to an apparatus for identifying characteristics of tissue which comprises, *inter alia*:

... an imaging system adapted to receive axial scan radiation based on the axial scan, receive data relating to the axial scan radiation that is based on at least one of **a spectral domain low-coherence interferometry or an optical frequency domain reflectrometry**, and process the data to automatically identify characteristics of the tissue.

As indicated above, the Izatt Patent only describes digital filters that are applied after the light has been detected – clearly the filters of Izatt are not optical filters. It is certainly known that both spectral domain low-coherence interferometry and an optical frequency domain reflectrometry perform ranging by detecting an electro-magnetic radiation as a function of wavelengths of the electro-magnetic radiation. However, the digital filters of the Izatt Patent do not perform such ranging, especially as a function of wavelengths of the electro-magnetic radiation. Therefore, the Izatt Patent fails to teach, suggest or disclose any imaging system adapted to receive data relating to the axial scan radiation that is based on a spectral domain low-coherence interferometry and/or an optical frequency domain reflectrometry, as explicitly recited in independent claim 41.

Accordingly, it is respectfully asserted that the Izatt Patent fails to teach, suggest or disclose the apparatus which comprises an imaging system adapted to receive data relating to the axial scan radiation that is based on a spectral domain low-coherence interferometry and/or an optical frequency domain reflectrometry, as explicitly recited in independent claim 41 of the above-identified application.

iii. Independent Claims 36 and 43

Applicants' invention, as recited in independent claim 36, relates to an apparatus for identifying characteristics of tissue which comprises, *inter alia*:

a radiation source configured to deliver radiation to the tissue; and

an imaging system configured to receive the radiation and process unidimensional data relating to the radiation to identify characteristics of the tissue.

Applicants' invention, as recited in independent claim 43, relates to an apparatus for identifying characteristics of tissue which comprises, *inter alia*:

... an imaging system adapted to receive the radiation and process unidimensional data relating to the radiation that is based on at least one of a spectral domain low-coherence interferometry or an optical frequency domain reflectrometry to identify characteristics of the tissue.

As an initial matter, in the Office Action, while alleging that the subject matter recited in independent claims 36 and 43 is disclosed in the Izatt Patent, the Examiner does not even point to any section of the Izatt Patent to disclose **processing unidimensional data relating to the radiation**, as explicitly recited in independent claims 36 and 43.

Indeed, the Izatt Patent does not teach, suggest or disclose the processing of unidimensional data which relates to radiation, much less to a spectral domain low-coherence interferometry and/or an optical frequency domain reflectrometry. It is submitted that the Izatt Patent describes processing multi-dimensional data, and not unidimensional data and especially that such processing is performed to identify the characteristics of the tissue.

Further, for at least the reasons as set forth herein above with respect to independent claim 41, the Izatt Patent fails to teach, suggest or disclose that **the radiation**

is based on a spectral domain low-coherence interferometry and/or an optical frequency domain reflectrometry, as also recited in independent claim 43.

Accordingly, it is respectfully asserted that the Izatt Patent fails to teach, suggest or disclose the apparatus which comprises an imaging system adapted to receive the radiation and process unidimensional data relating to the radiation (as recited in independent claims 36 and 43), much less that is based on at least one of a spectral domain low-coherence interferometry or an optical frequency domain reflectrometry to identify characteristics of the tissue (as explicitly recited in independent claim 43).

iv. Summary

Thus, for at least these reasons, withdrawal of the rejections of independent claims 1, 18, 24, 30, 36, 41 and 43 and the claims which depend therefrom under 35 U.S.C. §§ 102(b) and 103(a) is respectfully requested.

V. NEW CLAIM 44

New independent claim 44 has been added above to recite certain subject matter which Applicants believe includes novel features, and is separately patentable. Support for this new claim can be found in the originally-filed specification, drawing and claims. New independent claim 44 includes at least some of the features recited in claim 5.

Thus, for at least the reasons discussed above with respect to claim 5, Applicants respectfully asserts that the Izatt Patent fails to disclose, teach or suggest the subject matter recited in new independent claim 44.

VI. **CONCLUSION**

In light of the foregoing, Applicants respectfully submit that all pending claims 1, 2, 5-7, 9, 11-31, 33-36 and 40-44 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,



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